IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No.:	10/810,045	Confirmation No.	7893
Applicant:	Fred CHAPMAN et al.	Customer No.	53049
Filed:	March 26, 2004		
Examiner:	Jessica L. REIDEL		
Group Art Unit:	3766		
Docket No.:	PB10102.00		
Title:	DEFIBRILLATORS CUSTOMIZED FOR ANTICIPATED PATIENTS		

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Signature
Printed Name Mary Yawney Redman

APPEAL BRIEF

Mail Stop Appeal Brief – Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This an appeal from the Final Rejection mailed September 12, 2006. A Notice of Appeal was filed on December 12, 2006.

Please charge the fee of $500.00 required by 37 C.F.R. § 41.20(b)(2) for filing this Appeal Brief to Deposit Account No. 13-2546.

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REAL PARTY IN INTEREST

The real party in interest is Medtronic Physio-Control Corp. (now, by change of name, Physio-Control, Inc.) of Redmond, Washington

RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences.

STATUS OF CLAIMS

Claims 1-59 are pending.

Claims 1-18 and 46-59 are withdrawn from consideration.

Claims 30-33 and 43-45 are objected to.

Claims 19-29 and 34-42 are rejected.

Claims 19-29 and 34-42 are being appealed.

STATUS OF AMENDMENTS

The claims have not been amended under 37 C.F.R. § 1.116. The claims stand as listed in the Amendment filed June 28, 2006.

SUMMARY OF CLAIMED SUBJECT MATTER

Line numbers refer to the specification as originally filed. References to text and drawings are intended as examples and not as exhaustive lists of relevant text and drawing references.

(Claim 19) An external defibrillator (Fig. 1, no. 10) includes a therapy delivery module (Fig. 1, no. 24) and a processor (Fig. 1, no. 26). The processor is capable of determining whether a patient is one of an anticipated patient or a non-anticipated patient (Para. 0042, lines 1-3), where the anticipated patient is an individual patient associated with a patient-specific, customized profile (Fig. 2, no. 40A; Para. 0030, lines 4-6; Para. 0037) . The processor also is capable of controlling delivery of therapy (Para. 0036, lines 1-3) to the patient according to either a general

profile (if the patient is the non-anticipated patient) (Fig. 2, nos. 42A and 42B; Para. 0050, lines 3-4) or the customized profile (if the patient is the anticipated patient) (Fig. 2, no. 40A; Para. 0037, lines 1-6).

(Claim 21) The external defibrillator may further include an input circuit (Fig. 1, no. 34; Para. 0043, lines 5-8), where the processor receives an indication from a patient identification device associated with the anticipated patient (Fig. 1, no. 32; Para. 0043, lines 1-2) via the input circuit, and determines whether the patient is the anticipated patient based on the indication (Para. 0043, lines 3-4).

(Claim 22) The patient identification device may include an RFID device (Para. 0043, line 2).

(Claim 26) The external defibrillator may further include an input circuit (Fig. 1, no. 34; Para. 0043, lines 5-8). Where the customized profile (Fig. 6, no. 40) associated with the anticipated patient is stored within a memory associated with the patient (Fig. 6, no. 110; Para. 0061, lines 1-3), the processor retrieves the customized profile from the memory associated with the anticipated patient via the input circuit (Para. 0063, line 5), and determines that the patient is the anticipated patient based on receipt of the customized profile associated with the anticipated patient. The memory associated with the anticipated patient may include an RFID device that is interrogated by the external defibrillator (Para. 0062, lines 2-3).

(Claim 37) A computer-readable medium (Para. 0048, lines 1-3) includes instructions that cause a programmable processor to determine whether a patient is one of an anticipated patient or a non-anticipated patient (Para. 0042, lines 1-3), wherein the anticipated patient is an individual patient associated with a patient-specific, customized profile (Para. 0030, lines 4-6; Para. 0037). The computer-readable medium also includes instructions that cause a programmable processor to control delivery of therapy to the patient via an external defibrillator (Para. 0036, lines 1-3) according to either a general profile if the patient is the non-anticipated patient (Para. 0050, lines 3-4) or the customized profile if the patient is the anticipated patient (Para. 0037, lines 1-6).

(Claim 39) The instructions that cause the processor to determine whether a patient is an anticipated patient may include instructions that cause the processor to receive an indication from a patient identification device associated with the anticipated patient (Fig. 1, no. 32; Para. 0043, lines 1-2) .

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether claims 19, 21 24-25, 28-29, 34-35, 37, 39 and 41-42 are anticipated under 35 U.S.C. § 102(b) by U.S. Patent 5,836,993 to Cole (hereinafter "Cole");

2. Whether claims 22, 26-27 and 36 are unpatentable under 35 U.S.C. § 103(a) over Cole;

3. Whether claims 20 and 38 are unpatentable under 35 U.S.C § 103(a) over Cole in view of U.S. Patent 6,370,428 to Snyder (hereinafter "Snyder");

4. Whether claims 23 and 40 are unpatentable under 35 U.S.C. § 103(a) over Cole in view of U.S. Patent 5,285,781 to Brodard (hereinafter "Brodard"); and

5. Whether claim 36 is unpatentable under 35 U.S.C § 103(a) over Cole in view of U.S. Patent 6,141,584 to Rockwell (hereinafter "Rockwell").

ARGUMENTS

1. Claims 19, 21 24-25, 28-29, 34-35, 37, 39 and 41-42 rejected under 35 U.S.C. § 102(b) as being anticipated by Cole

In the Final Office Action (hereinafter "Action"), the Examiner rejected claims 19, 21, 24, 25, 28, 29, 34, 35, 37, 39, 41, and 42 under 35 U.S.C. § 102(b) as being anticipated by Cole. To support an anticipation rejection under 35 U.S.C. § 102, a prior art reference must disclose each and every element of a claim.[1] If a prior

[1] *See Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102 is improper.[2]

Cole fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, independent claims 19 and 37 require that a processor determine whether a patient is one of an anticipated patient and a non-anticipated patient. Both of these claims clearly define "anticipated patient" to mean "an individual patient associated with a patient-specific, customized profile" [emphasis added]. If the patient is the anticipated patient, claims 19 and 37 require that the processor control delivery of therapy according to that patient-specific, customized profile. Cole does not disclose these requirements of these independent claims.

In contrast, Cole describes potential patients for the electrotherapy device as follows:

> "The second memory may also be used to operate the electrotherapy device in a custom operation mode that differs from an operation mode provided by the first memory. For example, a defibrillator operating with instructions encoded on a first memory to treat adult patients may be transformed into a pediatric defibrillator by attaching a second memory containing instructions used by the controller to treat small children."[3]

In other words, Cole teaches treating two different classes of patients, pediatric and adult, with two different sets of instructions. Cole does not suggest controlling delivery of therapy according to a patient-specific, customized profile or according to a general profile, depending on whether the patient was determined to have a patient-specific customized profile associated with him or her, as required by the independent claims.

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[2] *Id. See also Lewmar Marine, Inc. v. Barient, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

[3] Cole, Col. 5, line 66 – Col. 6, line 6.

The Examiner's position is that since Cole's defibrillator treats one patient at a time, and since Cole's defibrillator can treat two different classes of patients (i.e., adult and pediatric), that Cole anticipates the claims referenced above. But to make this argument work, the Examiner has to argue that Cole's adult patient is non-anticipated but Cole's pediatric patient is "anticipated" as that word is defined in the claims.[4] In other words, the Examiner argues that: 1) one class of patients meets the definition of "anticipated" but the other class of patients does not, and 2) Cole's adult treatment instruction is a general profile but Cole's pediatric treatment instruction is a patient-specific customized profile. But both the adult and pediatric instructions of Cole are general in nature since they both apply to an entire class of patients. To call one "general" and the other "patient-specific, customized" is an erroneous argument, and it ignores the clear explanation in the Specification at, for example, Para. 0050, that a general profile may be a general adult profile or a general pediatric profile.

As another example, claims 21 and 39 require that the processor receives an indication from a patient identification device associated with the anticipated patient via an input circuit, and determines whether the patient is the anticipated patient based on the indication. Cole fails to teach the elements of claims 21 and 39. Contrary to the position stated in the Action[5], there is no patient identification device disclosed within the reference of Cole. The PC card described by Cole includes a memory, but there is no suggestion the PC card is in any way associated with an individual patient or that it identifies an individual to a processor.

Dependent claims 24-25, 28-29, 34-35, 37, 39, 41 and 42 are allowable for at least the reasons discussed above with respect to independent claims 19 and 37.

Cole fails to disclose each and every limitation set forth in claims 19, 21, 24-25, 28-29, 34-35, 37, 39, 41 and 42. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of Applicant's claims 19, 21, 24-25, 28-29, 34-35, 37, 39, 41 and 42 by Cole under 35 U.S.C. § 102(b).

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[4] See Action, page 3, lines 7-9
[5] See Action page 4, paragraph 6

2. Claims 22, 26-27 and 36 rejected under 35 U.S.C. § 103(a) as being unpatentable over Cole

In the Office Action, the Examiner rejected claims 22, 26-27 and 36 under 35 U.S.C. § 103(a) as being unpatentable over Cole. One of the requirements of a *prima facie* case of obviousness is that all limitations of the claim be shown to be in the prior art.[6] The arguments made above concerning the deficiencies of Cole are applicable here as well. Cole fails to disclose or suggest all the limitations of these claims, and provides no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

As an example, claim 22 requires that the patient identification device comprises a radio-frequency identification (RFID) device. Cole fails to provide any suggestion of a patient identification device that is associated with a patient. As discussed above in connection with the examiner's application of Cole to claims 21 and 39, the PC card described by Cole includes a memory, but there is no suggestion in Cole that the PC card is in any way associated with an individual. Further, the Examiner states that the RFID device is "an arbitrary design consideration which fails to patentably distinguish over Cole."[7] According to Cole, the PC card would fit into a "PC card slot"[8] ; the PC card does not provide or suggest wireless radio-frequency communication or the benefit therein. Therefore, there is no motivation to someone of ordinary skill in the art to modify the PC card of Cole to include an RFID device.

Also, Since Cole does not recognize the problem of identifying an individual person to a processor, Cole's teachings do not motivate one to modify its teachings to include an RFID device that can be associated with an individual patient (for example, by being worn).

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[6] See, e.g., *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (CAFC 1991).
[7] Office Action, Page 7.
[8] Cole, Col. 6, ll. 52-53.

Claim 26 requires that the memory associated with the anticipated patient comprises an RFID device that is interrogated by the external defibrillator. Cole's PC card does not store a patient-specific, customized profile and is not associated with any individual patient. Also, as mentioned above with respect to the deficiencies of Cole with respect to claim 22, Cole's PC card is not described or suggested to provide wireless radio-frequency communication or the advantage that wireless communication would provide. Therefore, there is no motivation to someone of ordinary skill in the art to modify the memory associated with the anticipated patient to include an RFID device.

For at least these reasons, the Examiner has failed to establish a prima facie case for unpatentability over Cole of Applicant's claims 20, 26-27 and 36 under 35 U.S.C. § 103(a) as over Cole.

3. Claims 20 and 38 rejected under 35 U.S.C § 103(a) as being unpatentable over Cole in view of Snyder

In the Office Action, the Examiner rejected claims 20 and 28 under 35 U.S.C. § 103(a) as being unpatentable over Cole in view of Snyder. As pointed out above, one of the requirements of a *prima facie* case of obviousness is that all limitations of the claim be shown to be in the prior art. This combination of references fails to disclose or suggest all the limitations of claims 20 and 38, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

The arguments made above concerning the deficiencies of Cole are applicable here as well. Snyder does not make up for any deficiencies in Cole. Snyder does not teach or suggest a determination of whether a patient is an individual patient associated with a patient-specific, customized profile, nor does Snyder teach or suggest controlling delivery of therapy according to a patient-specific, customized profile or according to a general profile, depending on whether the patient was determined to have a patient-specific customized profile associated with him or her.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 20, and 38 and 40 under 35 U.S.C. § 103(a) over Cole of view of Snyder.

4. Claims 23 and 40 rejected under 35 U.S.C. § 103(a) as being unpatentable over Cole in view of Brodard

In the Office Action, the Examiner rejected claims 23 and 40 under 35 U.S.C. § 103(a) as being unpatentable over Cole in view of Brodard. This combination of references fails to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Brodard discloses a device for electrical stimulation of skeletal muscle for muscular training and exercise.[9] Brodard does not contain any teachings on defibrillation or emergency medical therapy. The external defibrillator of Cole deals with an emergency medical device used in life-an-death cardiac emergencies. Brodard's muscular stimulation/exercise device deals with none of these things. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention absent some teaching, suggestion or incentive supporting the combination.[10] The problems, methods and functions associated with the external defibrillator of Cole and those associated with the electrical muscle exercise/stimulation device of Brodard are so dissimilar that there is no teaching, suggestion or incentive supporting the combination, and these two references are not properly combined.

But even assuming for the sake of argument that these references are combinable, the combination does not support a prima facie case of obviousness. As pointed out above, one of the requirements of a *prima facie* case of obviousness is

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[9] See Brodard Abstract.

[10] See, e.g., *ACS Hospital Systems, Inc. v. Montefiore Hospital*, 732 F.2d 1572, 1577 (Fed. Cir. 1984).

that all limitations of the claim be shown to be in the prior art. The combination of Cole and Brodard does not disclose all the limitations of claims 23 and 40, and there is no suggestion in the references of the desirability of modifying their teachings to arrive at the claimed invention. The arguments made above concerning the deficiencies of Cole are applicable here as well and Brodard does not make up for the deficiencies in Cole's teachings.

For example, Brodard does not disclose or suggest any controlling of therapy delivery according to a patient-specific, customized profile or to a general profile, depending on whether the patient is determined to be an individual patient associated with a patient-specific, customized profile, as required by the independent claims from which claims 23 and 40 depend.

For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 23 and 40 under 35 U.S.C. § 103(a) as unpatentable over Cole in view of Brodard.

5. Claim 36 rejected under 35 U.S.C § 103(a) as being unpatentable over Cole in view of Rockwell

In the Office Action, the Examiner rejected claim 36 under 35 U.S.C. § 103(a) as being unpatentable over Cole in view of Rockwell. As pointed out above, one of the requirements of a *prima facie* case of obviousness is that all limitations of the claim be shown to be in the prior art. This combination of references fails to disclose or suggest the inventions defined by claim 36, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

The discussion above concerning the deficiencies of Cole is applicable here as well, and Rockwell in no way supplies what is lacking in Cole. Rockwell does not disclose or suggest determination of whether a patient is an individual associated with a patient-specific, customized profile or a controlling delivery of therapy according to a patient-specific, customized profile or according to a general profile, depending on whether the patient was determined to have a patient-specific customized profile

associated with him or her, as required by the independent claim from which claim 36 depends.

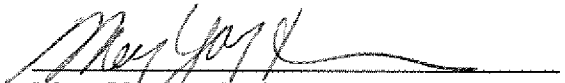
For at least these reasons, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claim 36 under 35 U.S.C. § 103(a) over Cole in view of Rockwell.

CONCLUSION

For the reasons given above, the rejections of claims 19, 21 24-25, 28-29, 34-35, 37, 39 and 41-42 under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) are erroneous and should be reversed. The Examiner has failed to meet the burden of establishing prima facie cases of anticipation and obviousness for the claims on appeal. In view of Appellants' argument, the final rejections of these claims are improper and should be reversed.

Respectfully submitted,

Date: February 12, 2007



Mary Yawney Redman
Registration No. 29,881

Physio-Control, Inc.
P.O. Box 97006
Redmond WA 98073-9706

Telephone: 425-867-4465
Facsimile: 425-867-4142

CLAIMS APPENDIX

The claims on appeal are as follows:

19. An external defibrillator comprising:

a therapy delivery module; and

a processor to determine whether a patient is one of an anticipated patient or a non-anticipated patient, wherein the anticipated patient is an individual patient associated with a patient-specific, customized profile, and to control delivery of therapy to the patient by the therapy delivery module according to one of a general profile if the patient is the non-anticipated patient or the customized profile if the patient is the anticipated patient.

20. The external defibrillator of claim 19, further comprising a user interface, wherein the processor receives an indication from a user via the user interface, and determines whether the patient is the anticipated patient based on the indication.

21. The external defibrillator of claim 19, further comprising an input circuit, wherein the processor receives an indication from a patient identification device associated with the anticipated patient via the input circuit, and determines whether the patient is the anticipated patient based on the indication.

22. The external defibrillator of claim 21, wherein the patient identification device comprises a radio-frequency identification (RFID) device.

23. The external defibrillator of claim 19,

further comprising at least one of a user interface and an input circuit,

wherein the processor receives information identifying the patient via at least one of the user interface and the input circuit, selects one of a plurality of

patient-specific, customized profiles based on the identification, each of the customized profiles associated with a respective one of a plurality of anticipated patients, and controls delivery of therapy according to the selected customized profile.

24. The external defibrillator of claim 19,

further comprising an input circuit,

wherein the customized profile associated with the anticipated patient is stored within a memory associated with the patient, and

wherein the processor retrieves the customized profile associated with the anticipated patient from the memory associated with the anticipated patient via the input circuit, and determines that the patient is the anticipated patient based on receipt of the customized profile associated with the anticipated patient.

25. he external defibrillator of claim 24, wherein the memory associated with the anticipated patient is a removable medium for the external defibrillator.

26. The external defibrillator of claim 24, wherein the memory associated with the anticipated patient comprises a radio frequency identification (RFID) device that is interrogated by the external defibrillator.

27. The external defibrillator of claim 24, wherein the memory associated with the anticipated patient comprises a memory within a consumer electronic device of the anticipated patient.

28. The external defibrillator of claim 24, wherein the memory associated with the anticipated patient comprises a memory that is accessible by the external defibrillator via a network.

29. The external defibrillator of claim 19, wherein the profiles comprise defibrillation therapy parameters, and the processor controls delivery of defibrillation according to the defibrillation therapy parameters of one of the profiles.

34. The external defibrillator of claim 19, further comprising a memory that stores the customized profile associated with the anticipated patient.

35. The external defibrillator of claim 19, further comprising a memory that stores the general profile.

36. The external defibrillator of claim 19, wherein the external defibrillator comprises an automated external defibrillator (AED).

37. A computer-readable medium comprising instructions that cause a programmable processor to:

determine whether a patient is one of an anticipated patient or a non-anticipated patient, wherein the anticipated patient is an individual patient associated with a patient-specific, customized profile; and

control delivery of therapy to the patient via an external defibrillator according to one of a general profile if the patient is the non-anticipated patient or the customized profile if the patient is the anticipated patient.

38. The medium of claim 37, wherein the instructions that cause the processor to determine whether a patient is an anticipated patient comprise instructions that cause the processor to receive an indication from a user via a user interface of the external defibrillator.

39. The medium of claim 37, wherein the instructions that cause the processor to determine whether a patient is an anticipated patient comprise

instructions that cause the processor to receive an indication from a patient identification device associated with the anticipated patient.

40. The medium of claim 37, further comprising instructions that cause the processor to:

receive information identifying the patient; and

select one of a plurality of patient-specific, customized profiles based on the identification,

wherein each of the patient-specific, customized profiles is associated with a respective one of a plurality of anticipated patients, and the instructions that cause the processor to control delivery of therapy comprise instructions that cause the processor to control delivery of therapy according to the selected customized profile.

41. The medium of claim 37,

wherein the customized profile associated with the anticipated patient is stored within a memory associated with the patient, the medium further comprising instructions that cause the processor to retrieve the customized profile associated with the anticipated patient from the memory associated with the anticipated patient, and

wherein the instructions that cause the processor to determine whether a patient is an anticipated patient comprise instructions that cause the processor to determine that the patient is the anticipated patient based on receipt by the external defibrillator of the customized profile associated with the anticipated patient from the memory associated with the anticipated patient.

42. The medium of claim 37, wherein the profiles comprise defibrillation therapy parameters, and the instructions that cause the processor to control delivery of therapy comprise instructions that cause the processor to control delivery of defibrillation therapy to the patient based on the parameters of one of the profiles.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.